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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |
|--|-------------|----------------------|-------------------------|------------------|
| 10/700,344   | 11/03/2003  | Andrew L. Cote SR.   | 1600/163                | 5277             |
| 2101 7590 06/16/2009 BROMBERG & SUNSTEIN LLP 125 SUMMER STREET |             |                      | EXAMINER                |                  |
|  |             |                      | MOULTON, ELIZABETH ROSE |                  |
| BOSTON, MA 02110-1618  |             |                      | ART UNIT                | PAPER NUMBER     |
|  |             |                      | 3767                    |                  |
|  |             |                      |                         |                  |
|  |             |                      | MAIL DATE               | DELIVERY MODE    |
|  |             |                      | 06/16/2009              | PAPER            |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

|  | Application No.   | Applicant(s) |  |  |  |  |
|--|---|--------------|--|--|--|--|
|  | 10/700,344  | COTE ET AL.  |  |  |  |  |
| Office Action Summary  | Examiner  | Art Unit     |  |  |  |  |
|  | ELIZABETH R. MOULTON  | 3767         |  |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address<br>Period for Reply  |   |              |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |   |              |  |  |  |  |
| Status   |   |              |  |  |  |  |
| 1)⊠ Responsive to communication(s) filed on <u>08 M</u>  | av 2009   |              |  |  |  |  |
|  | action is non-final.  |              |  |  |  |  |
| <i>;</i> —   | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is |              |  |  |  |  |
|  | closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.               |              |  |  |  |  |
| Disposition of Claims  |   |              |  |  |  |  |
| 4)⊠ Claim(s) <u>37,40-47,49,63,65-73 and 93-110</u> is/are pending in the application.   |   |              |  |  |  |  |
| 4a) Of the above claim(s) is/are withdrawn from consideration.   |   |              |  |  |  |  |
| 5) Claim(s) is/are allowed.  |   |              |  |  |  |  |
| 6)⊠ Claim(s) <u>37,40-47,49,63,65-73 and 93-110</u> is/are rejected.   |   |              |  |  |  |  |
| 7) Claim(s) <u>37,49-47,49,03,03-73 and 93-770</u> is/are rejected. 7  |   |              |  |  |  |  |
| 8) Claim(s) are subject to restriction and/or  | election requirement  |              |  |  |  |  |
|  | oloonon roquironnonni   |              |  |  |  |  |
| Application Papers   |   |              |  |  |  |  |
| 9) The specification is objected to by the Examiner.   |   |              |  |  |  |  |
| 10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.  |   |              |  |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  |   |              |  |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).   |   |              |  |  |  |  |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.   |   |              |  |  |  |  |
| Priority under 35 U.S.C. § 119   |   |              |  |  |  |  |
| <ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>  |   |              |  |  |  |  |
| Attachment(s)  1) Notice of References Cited (PTO-892)   | 4) Interview Summary  |              |  |  |  |  |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  Paper No(s)/Mail Date  Notice of Informal Patent Application  |   |              |  |  |  |  |
| Paper No(s)/Mail Date 6) Other:  |   |              |  |  |  |  |

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#### **DETAILED ACTION**

## **Priority**

This applicant claims the benefit of provisionals 60/031,175 and 60/034,708. Because application 09/479,327 was not filed within one year of those provisionals, this application is entitled to a priority date of 1/27/1999 (the filing date of provisional 60/117,359).

# Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- 2. Claims 37, 40-47, 49, 63, 65-73, and 93-110 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Cote (WO 98/22178).
- See Fig 1-3. This document was published 28 May 1998, less than one year before the current application's filing date of 27 January 1999.

### Claim Rejections - 35 USC § 103

- 3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 37, 40-47, 49, 63, 65-73, and 93-110 are rejected under 35 U.S.C. 103(a) as being unpatentable over Patzer (US 5,578,059) in view of Paradis et al (US 5,190,067)

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Claims 37, 63, 93, 102, Patzer teaches (Fig 1-4):

A housing (16) defining a passageway (41 and downward), having an inlet (76) and an outlet (22);

A plug member (26) moveably mounted within the passageway (Fig 1and Fig 4), the plug member being a cannula and defining a channel (36) there through;

A substantially flexible resilient gland member (14) secured to the housing (by nipple 32 of housing 17) and the plug member (as shown in Fig 4), the plug member supported within the passageway by the gland;

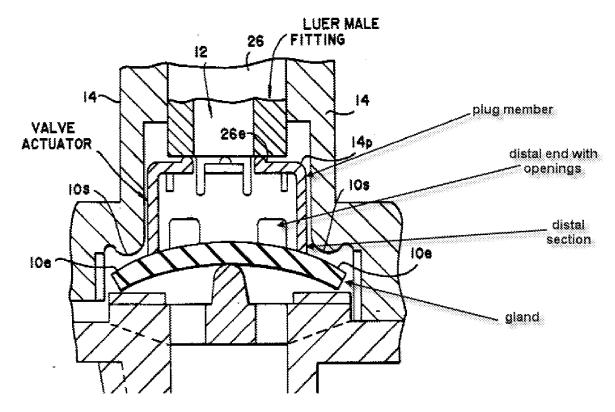
Wherein the plug member is substantially rigid (does not deform in moving from Fig 1 to Fig 4), wherein the plug has a proximal end (top Fig 1 or 4) and a distal end (bottom), and a distal section (distal most end), having an opening nearer the distal end (channel 36 extends through the plug), the gland member normally occluding the opening (Fig 1).

Patzer shows a minute gap between the distal end portion of the plug and the gland (see G in response filed 5.8.09 page 3).

Paradis shows a valve with a moveable plug (valve actuator 14p) supported by a gland (10e) (see Fig 1A-1B). There is no gap between the gland and the plug in the closed position of the valve. Paradis disclosed that the gland is "held against" the plug. See Fig 1B as labeled below, showing valve in the open position (close-up of the valve)

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to have the gland and plug contact each other as taught by Paradis to prevent any leakage of fluids out of the plug member openings prior to depression of the plug.

As to claims 40-43, 45, 46, 49, 65-68, 70, 71, 73, 94-96, 98, 99, 101, 103-105, 107, 108, and 110, see Figs 1-4 which clearly show the claimed open/closed configurations.

As to claims 44, 69, 97, and 106 the gland has seal section (28), the inlet has an exterior face (12), the seal section being substantially aligned (coaxial) which the exterior face then the valve is closed to provide a swabable surface (56)

As to claims 47, 72, 100 and 109 the plug (36) has different cross-hatching than the gland (14) indicating that they are different materials.

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### Response to Arguments

5. Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection.

#### Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH R. MOULTON whose telephone number is (571)272-9970. The examiner can normally be reached on 7:00-3:30 M-Th.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ELIZABETH R MOULTON/ Examiner, Art Unit 3767 /Kevin C. Sirmons/ Supervisory Patent Examiner, Art Unit 3767